DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

D1332B

August 1, 1997

WARNING LETTER
CHI-38-97

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Jeffrey Gerchenson, President
Alva-Amco Pharmacal Co., Inc.
6625 Avondale Avenue
Chicago, IL 60631

Dear Mr. Gerchenson:

This is in reference to "herpetrol coated tablets" which is marketed by your firm. The product labeling indicates that this product contains L-lysine monohyrochloride, and six vitamins and minerals. "Herpetrol" is labeled as "A unique combination of natural ingredients for dietary supplement use, to help provide amino balance and nutritional support for persons suffering with cold sores and fever blisters", and "to deal with cold sores, fever blisters, and related canker sores."

The Dietary Supplement Health and Education Act (DSHEA) became law on October 25, 1994, and amended the Federal Food, Drug, and Cosmetic Act (FFDCA). DSHEA provides that a dietary supplement is a food under Section 201(f), unless it falls within the definition of "drug" as found in Section 201(g) of the FFDCA. DSHEA allows marketers of dietary supplements to make truthful and not misleading structure/function claims in accordance with Section 403(r)(6) of the FFDCA without subjecting such products to regulation as drugs. However, such claims or statements may not claim to diagnose, prevent, mitigate, treat, or cure a specific disease or class of diseases.

"Herpetrol" does not comply with the requirements of Section 403(r)(6) of DSHEA which mandates that labeling for dietary supplements must indicate that any statement made "has not been evaluated by the Food and Drug Administration." FDA has evaluated L-lysine hydrochloride and has determined that neither this nor any other ingredient is generally recognized as safe and effective to treat or relieve the symptoms or discomfort of fever blisters and cold sores. Accordingly, you cannot truthfully include the statement required under Section 403(r)(6)(C) for "herpetrol."

Based on its "herpetrol" trade name and labeled uses to "deal with cold sores, fever blisters and related canker sores," this product is a drug under Section 201(g). "Herpetrol" is also a new drug as described in Section 201(p) of the FFDCA which may not be legally marketed in the United States since it is not approved as stated in Section 505(b). This drug is also misbranded as described in Section 502(f)(1) because the labeling fails to bear adequate directions for the labeled indications.

The above list of violations is not intended to be an all-inclusive of those that exist at your firm. It is your responsibility to ensure that the drug products you market meet all requirements of the Act and its implementing regulations. Federal agencies are advised on the issuance of Warning Letters about drugs and devices so that they may take this information into account when considering the award of contracts.

We request that you take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action without further notice. This action may include seizure and/or injunction

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific actions you will take to correct the violations. Your response should include an explanation of each step being taken to prevent recurrence of similar violations. If corrective action cannot be completed within 15 working days, please state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the attention of Jerome Bressler, Assistant District Director, Compliance.

Sincerely,

/S/

Raymond V. Mlecko
District Director